FDA Part 11 Compliance Committee's Summary of the Public Conference on the Technical Implementation of 21 CFR Part 11 (Electronic Records; Electronic Signatures) held on June 19 & 20, 2000 at the Wyndham Franklin Plaza Hotel, Philadelphia, PA:

Part 11 affords persons substantial flexibility in selecting enabling technologies that meet their respective needs, yet facilitate compliance with the rule. However, the Food and Drug Administration (FDA) is aware that some individuals have found it challenging to keep up with available technologies and adapt them to older electronic recordkeeping systems. The Agency is mindful of the rapid pace at which such technologies are changing and emerging, and the importance of keeping up with products and services that help ensure that electronic records remain trustworthy, reliable, and compatible with FDA's public health protection responsibilities.

With these concerns in mind, the FDA and the Parenteral Drug Association (PDA) co-sponsored this event on industry's experience in implementing the technical provisions of regulations (21 CFR Part 11) on electronic records and electronic signatures.

This meeting was open to all FDA regulated industries as well as suppliers of computer technologies and services designed for use with electronic records. Attendees had an opportunity to ask questions of presenters.

In attendance were 900 individuals, the majority from pharmaceutical and medical device industries, although other FDA regulated industries were also represented. The large number of attendees clearly underscored the rapidly growing interest in this subject.

The scope of this meeting was limited to experience in implementing Part 11's technical requirements. The main objectives were to:

- Hold an open forum for exchanging information among the regulated industries on their experiences in implementing the rule's technical provisions; and,

- Have a better understanding of the currently available and future tools/resources that enable persons to comply with those technical requirements.

We intend to use the outcome of the conference to assist the Committee in preparing industry guidance documents. Based on our assessment of the meeting and comments received from attendees, we conclude that our objectives were met.

This meeting was not intended to be a forum to discuss the merits of the rule, nor a tutorial on the regulation. It was also expected that attendees would have a basic understanding of Part 11. However, it was evident by the nature of questions posed to our panelists and attendee comments that many attendees had different expectations for this meeting. We believe this may indicate that some attendees either misunderstood or did not read the meeting's description statements presented in the Federal Register notice, the Agency's web site and in PDA's literature and web site.

During the conference, we listened to 22 speakers from the regulated industry, service providers, and other parties in electronic commerce and electronic government. The presentations covered:

- Archiving procedures;
- Record integrity and audit trails;
- Electronic signatures; and,
- Electronic recordkeeping in clinical studies.

The following themes emerged from the conference:

- Agency guidance to industry is needed, and soon. Industry would like the guidance to be issued in a modular manner, with easier issues addressed first and more complex issues covered later;
- Products and services are currently available to enable compliance with Part 11 technical provisions. However, the solutions are available as a mosaic of parts that firms must assemble on a case by case basis to meet their individual needs. Among the adaptable solutions we heard about were:

reusable code, XML, Java and Active X, Windows NT access and security controls, and source code versioning control software. Persons are unlikely to find turnkey, "one size fits all" applications.

- Providers of products and services that enable Part 11 compliance are prepared to meet the needs of their clients. Suppliers would like stability in requirements, and their customers need to be specific in the features they desire, rather than asking broadly for "Part 11 compliance." Service providers are able to provide needed solutions quickly; one speaker commented that software revisions could be prepared in as few as six months.
- Part 11 technical provisions exist in the domains of electronic commerce and electronic government. Other industries have already achieved the rule's objectives.

It was evident that all present recognized the increasing importance and need for using electronic records and signatures, as well for compliance with this regulation. Part 11 was recognized as a "sentinel regulation" that other regulatory bodies may emulate.

We retained the compilation of audience questions for use in preparing guidances.

In his conference closing remarks, Mr. John Marzilli, Deputy Associate Commissioner for Regulatory Affairs, stated the FDA's commitment to preparing Part 11 guidance on subjects that include:

- Systems validation;
- Audit trails;
- Time stamps;
- General security;
- Archiving; and,
- Predicate rule considerations in identifying what a required record is

Mr. Marzilli also said that FDA would follow its good guidance practices in developing the documents. He added that we will hear

from all interested parties and hold constructive dialog on a continuing basis, as the Part 11 Compliance Committee has already done, and we will continue that exchange in order to consider a variety of views and technical approaches. He also stated that, like the rule itself, our guidance will afford persons the maximum flexibility in selecting from a broad range of technologies.

Mr. Marzilli emphasized, however, that FDA, and FDA alone, has the task of preparing and issuing FDA guidance to industry, and that we cannot collaborate with one or more entities to the exclusion of others.

Mr. Marzilli concluded by saying that the guidance, and our overall implementation of Part 11 will be shaped not only by industry input, but also:

- Our field experience with the rule (problems we continue to find that impact product quality and safety and data integrity);
- Emerging products and services;
- Technology trends; and,
- The influences of electronic government and electronic commerce.

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